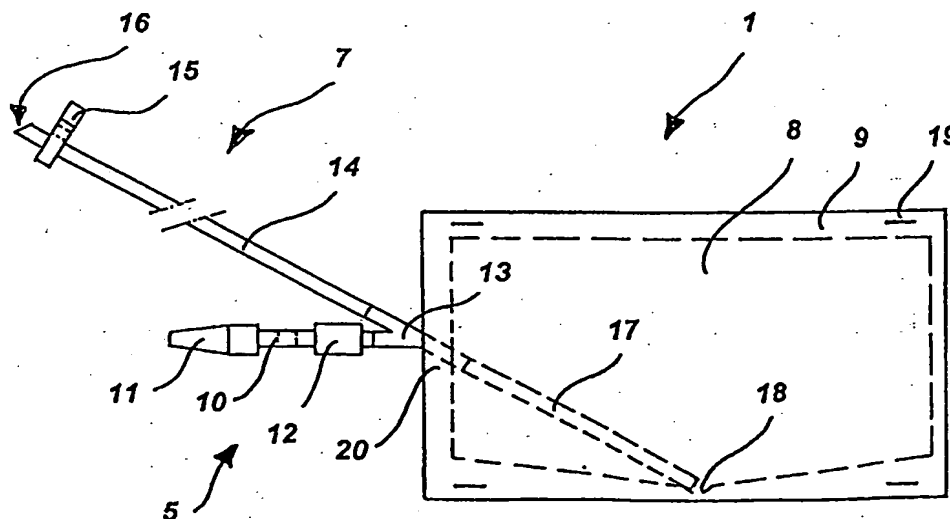




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(21) International Application Number: PCT/DK98/00479 (22) International Filing Date: 6 November 1998 (06.11.98) (30) Priority Data: 1268/97 7 November 1997 (07.11.97) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebæk (DK). (72) Inventors; and (75) Inventors/Applicants (for US only): TANGHOEJ, Allan [DK/DK]; Jellerød Have 59, DK-2980 Kokkedal (DK). JOERGENSEN, Thomas, Friis [DK/DK]; Myremosevej 24, DK-2990 Nivaa (DK). (74) Agent: COLOPLAST A/S; Patent Dept., Attn.: Kim Nilausen, Høltedam 1, DK-3050 Humlebæk (DK).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: A URINE COLLECTION BAG



(57) Abstract

A urine collection bag (1, 21) comprising front and rear walls formed of polymer material, said walls having edges sealed together, an inlet (5, 25) for transporting urine into the urine collection bag, an outlet (7, 27) for emptying urine from the collection bag, said outlet comprising a siphon (17) and provided with an outlet valve (15). The inlet (5, 25) and outlet (7, 27) have a common lead-in in the bag.

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TITLE

A urine collection bag.

FIELD OF THE INVENTION

The present invention relates to bags for collecting liquid secretions from a
5 human body, especially urine collection bags suitable for people being chair
bound due to paralysis (for example tetraplegia, paraplegia, sclerosis and spina
bifida), as well as to methods for producing such devices.

BACKGROUND OF THE INVENTION

GB patent application No. 2 145 058 discloses a urine collection bag comprising
10 front and rear walls formed of polymer material, said walls having edges sealed
together, an inlet adapted for transporting urine into the urine collection bag, an
outlet for emptying urine from the collection bag, said outlet comprising a siphon
for emptying the urine collection bag. This drainage bag is directed for users
having an urostomy and who are not dexterous, and particularly those who are
15 old and infirm. These people find it difficult to satisfactorily manipulate present
bag-emptying arrangements involving e.g. a tube with a clip, a valve or a tap.

This known device cannot be used by people with paralysis, as these people
often suffers from spasms which could very easily result in sudden and
unexpected emptying of the bag causing extreme discomfort and embarrass-
20 ment.

Conventional urine collection bags for day use and suitable for being connected
to a urine transporting or collecting device as e.g. a catheter or a urisheath are
normally carried in a hidden position under the clothing. Most frequently the bag
is worn under the trousers fastened to the leg by some fastening device such as
25 straps and the like. An outlet comprising a suitable closing device such as a
valve is provided in order to empty the bag during the day, said outlet being
operational in a position under the lower edge of the trousers close to the foot.
However these conventional urine collection devices cannot be used by people
suffering from paralysis in the lower part of the body without great difficulty, as

they have to place the paralysed leg on the edge of a toilet and reach down to the foot before opening the valve. At the same time one should bare in mind that people with paralysis often lack the control of their stomach muscles, which means that they have to use one hand keeping hold on the back of the wheel-
5 chair in order not to tip forward and fall out of the chair. This leaves them with only one hand to do all the other operations (lifting their trouser leg, pointing the outlet, operating the valve, supporting the outlet during the entire emptying operation). If there is no access to a toilet the emptying of the bag is often carried out in a urinal. In this case the paralysed person needs an extra hand to
10 hold the urinal and is forced to seek assistance.

German patent No. 32498 discloses a urine collection device having a security vent and a siphon outlet, provided with an outlet valve, and a urisheath. The urine collection device is provided with a ventilation system, ensuring inlet of air when the bag is emptied and outlet of air when urine flows into the bag. This
15 urine collection device comprises many parts which makes it complex to manufacture.

Different solutions have been proposed for providing a wheelchair with a urine collection device. DK Design registration No. 0641 1991 discloses such a wheelchair. However this device is a simple container mounted underneath the wheel-
20 chair and in which the chair bound person urinates. This chair is mostly used at hospitals and is not suitable for people who wants to lead as normal a life as possible, as the system is not closed and does not provide security against leakage.

The use of non-return valves in connection with collection bags is well known per
25 se, and is for example disclosed in the following references.

British Patent Application No. 2 313 430, British Patent Application No 2 171 315 and US Patent No. 4 723 944.

There is still a need for an improved collection bag being simple to produce and being simple to use without risk of leakage.

It is the object of the invention to provide an improved urine collection bag comprising a siphon outlet and a non return valve, and being simple and inexpensive to produce.

It is a further object of the invention to provide a urine collection bag especially
5 suitable for people being chair bound, by which device paralysed people should be able to empty the urine collection bag without the risk of falling out of their wheelchair, without having the troubles of placing one leg on the edge of a toilet, without the need of assistance in case there is no access to a toilet and without the risk of spillage on the trousers, the sock or in the shoe.

10 Yet another object of the invention is to provide a method for producing a preferred embodiment of such a urine collection device.

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates, in its broadest aspect, to a urine collection bag comprising front and rear walls formed of polymer material, said walls having
15 edges sealed together, an inlet for transporting urine into the urine collection bag, an outlet for emptying urine from the collection bag, said outlet comprising a siphon and the outlet is provided with an outlet valve.

Further, the invention relates to an assembly joint for a urine collection bag comprising an inlet and an outlet, wherein the assembly joint comprises two
20 parts, a first part made of a dimensionally stable material and comprising an inlet section and an outlet section through which fluid can pass, and a second part made of a resilient material which part in a closed position completely covers the inlet section through which the fluid enters the collection bag through the first part.

25 BRIEF DESCRIPTION OF THE DRAWINGS

Below embodiments of a urine collection bag according to the invention and components of same will be explained in more detail with reference to the drawings, in which

Fig. 1 illustrates a paralysed person sitting in a wheelchair with a urine collection bag according to a first embodiment of the invention.

Fig 2 illustrates the urine collection bag according to Fig. 1 in a larger scale.

Fig. 3 illustrates a paralysed person sitting in a wheelchair with the urine collection bag according to a second embodiment of the invention fastened to the wheelchair.

Fig. 4 illustrates the urine collection bag according to a third embodiment of the invention.

Fig. 5 illustrates a urine collection bag according to a fourth embodiment of the invention.

Fig. 6 illustrates a urine collection bag according to a fifth embodiment of the invention.

Fig. 7 illustrates the assembly joint of the urine collection bag according to Fig. 6, and

Fig. 8 illustrates in cross-section the return-valve of the assembly joint according to Fig. 6 and 7.

DETAILED DESCRIPTION OF THE INVENTION

In a first aspect, the invention relates to a urine collection bag comprising front and rear walls formed of a suitable polymer material such as PVC, PP or PE, said walls having edges sealed together, an inlet for transporting urine into the urine collection bag, an outlet for emptying urine from the collection bag, said outlet comprising a siphon and is provided with an outlet valve, wherein the inlet and the outlet have a common lead-in in the bag.

When the urine collection bag has a common lead-in in the bag it is more secure against spillage as the periphery of the bag is only interrupted at one site.

When the user needs to empty this bag he retrieves the outlet tube from under his trousers, he then opens the outlet valve (he has two hands free for this purpose) and places the valve opening at the end of the outlet tube into the recipient container (e.g. a urinal). Then he squeezes on the bag until urine begins to flow through the outlet valve whereafter the urine will be siphoned out without further pressure on the bag.

The user can manoeuvre this device while sitting in his wheelchair, without having to be afraid of losing the balance and tilting forward or having to ask anyone for help.

The urine collection bag is not limited to be used together with a urine collection device like a catheter or a urisheath, the person skilled in the art will understand that it can be connected to a lot of different kinds of collecting devices like e.g. female urinary collecting devices.

In a preferred embodiment of the invention the inlet and the outlet form a common tube member communicating between the substantially lowest point of the urine collection bag and the point where the inlet is connected to the outlet device.

The common tube member, the inlet and the outlet may be connected by a T- or Y shaped connector.

It is advantageous to provide the inlet of the urine collection bag according to the invention with a non-return valve, as the urine in the bag will tend to flow backwards when the bag is compressed. Providing the inlet with a non-return valve or a similar device therefore ensures a free flow of urine into the bag and reduces the risk of infection.

Fig. 1 illustrates a person 2 sitting in a wheelchair 4. A urine collection bag 1 is fastened to the users left leg 3a. The users right leg is schematically cut off at 3b in order to show the urine bag and the urisheath 6.

- Fig. 1 and 2 illustrate a preferred embodiment of the urine collection bag 1 according to the invention, wherein the inlet 5, comprising a tube member 10, a connector 11 for connecting the urine collection bag 1 to an urisheath 6 and a non-return valve 12, which inlet 5 is connected with the outlet 7, comprising a elongated tube member 14, an outlet valve 15 and an end 16, and wherein the inlet and outlet of the bag 8 are provided in the form of a common tube member 17 communicating between the substantially lowest point 18 of the urine collection bag 8 and the point 20 where the inlet device 5 is connected to the outlet device 7 and passes through the edge 9 of the bag 8, and wherein the common tube member 17 together with the outlet device acts as the part of siphon when the outlet valve 15 of the outlet device 7 is in open position. As it can be seen on this specific embodiment the inlet 5 and the outlet 7 are connected to each other and the connection is in the form of a substantially Y-shaped tubing 13, where part of the siphon 17, being placed internally in the bag 8 is the bottom leg of the Y, and the outlet tube and inlet tube are the two top legs. The tubing could also be of T-shape or other suitable shapes.
- As it is illustrated in Fig. 2 the urine collection bag 1 according to this preferred embodiment of the invention is characterised in that the inlet 5 and the outlet 7 have a common site 20 where they pass the walls of the bag 8. In this case this site is at the edge 9 of the bag 8.

- In all embodiments of urine collection bag according to the invention the inlet and the outlet constituting the siphon may be made from flexible tubes. In Fig. 2 the connecting member 13 is fastened at the edge of the collection bag. This fastening could be carried out by a welding process, known per se for connecting tubes with collection bag.

- The embodiment of the urine collection bag 1 shown in Fig. 1 and 2 is provided with fastening means, for fastening the bag to the users leg. In this embodiment

the bag is fastened on the inner side of the users leg 3a. The fastening means shown in Fig. 2 are straps, being fastened around the users leg. All other suitable fastening means known by the person skilled in the art may be used.

The urine collection bag may e.g. be provided with fastening means for fastening
5 it to a wheelchair.

In order to make the urine collection bag more comfortable at least one of the outer walls may be provided with a soft backing.

Further, at least the front wall of the urine collection device may be transparent and at least the front wall may be provided with measuring means for measuring
10 the amount of urine collected in the bag.

Fig. 3 illustrates another preferred embodiment according to the invention, wherein the urine collection bag 21 is provided with fastening means 39a, 39b for fastening it to a wheelchair 24. When placing the urine collection device 21 on the wheelchair a much larger bag may be used, which do not need to be emptied
15 very often. Of course the urine collection bag should be hidden under some kind of protection device in order not to show in public. A further advantage is that the person 22 is more free to choose his or her garments. During summer time shorts or miniskirt could easily be used. The garments could just be provided with a zip, or small hole in the side for making a passage for the inlet. The
20 person 22 would feel much more free, as the major part of the equipment, comprising the bag and the outlet, has been removed from the body, only the urisheath 26 is close to his body and no bag is fastened to his leg 23a.

Further embodiments of the urine collection bag according to the invention are shown in Figs. 4 and 5. The inlet 45, 65 comprises a connector 51, 71 for
25 connecting the urine collection bag 41, 61 to a urisheath, a catheter or a similar urine transporting device. The outlet 47, 67 comprises an elongated tube member and an outlet valve 55, 75. In these embodiments the urine collection bags 41, 61 are provided with a flange member 53, 73. This flange member 53, 73 functions as the connection member between the inlet 45, 65 and the outlet
30 47, 67. The flange member 53, 73 is placed on top of a not shown hole in one of

the walls of the bag 48, 68 in order to provide the communication between the inlet and the inside of the bag 48, 68 and between the outlet 47, 67 and the inside of the bag 48, 68. In Fig. 4 the flange member 53 is further connected to a tube member 57, acting as part of the siphon and communicating between said
5 flange and the lowest point 58 of the bag 48. In Fig. 5 the flange member 73 is placed at the lowest point 78 of the bag 68. A non-return valve 52, 72 is provided as a part of the flange member 53, 73.

In a further preferred embodiment of the invention the inlet and the outlet of the urine collection bag are connected to each other by an assembly joint.

- 10 This assembly joint may be arranged between the two walls of the bag at the periphery of same, and may comprise a non-return valve. By providing the non-return valve in the assembly joint the whole collection device becomes more simple and inexpensive to produce. The assembly may be secured to the walls of the bag by gluing or welding.
- 15 According to a yet another preferred embodiment of the invention the assembly joint for a urine collection bag comprising an inlet and an outlet, wherein the assembly joint comprises two parts, a first part made of a dimensionally stable material and comprising an inlet section and an outlet section through which fluid can pass, and a second part made of a resilient material which part in a closed
20 position completely covers the inlet section through which the fluid enters the collection bag through the first part, and wherein the second part has a plate like form and is secured to a surface of the first part which surface faces the inside of the collection bag and surrounds the inlet section through which fluid enters the collection bag.
- 25 According to the invention the assembly joints characterised in that the surface to which the second part is secured is encircled by walls parallel to the flow direction.

Fig. 6 illustrates a urine collection device comprising a urine collection bag, an inlet, an outlet with an outlet valve, an assembly joint, and a siphon. As it

appears from the drawing the assembly joint is arranged at the periphery of the bag.

At Fig. 7 the assembly joint 92 of Fig.6 is illustrated in exploded view in perspective. This preferred assembly joint 92 comprises an inlet section and an outlet section. The inlet section comprises a short tube-shaped connector 105 for the inlet tube 85 and a non-return valve 112. The outlet section of the assembly is provided with a short tube-shaped connector 107 for the outlet tube 87 and a short tube-shaped connector 117 for the siphon tube 97. The assembly joint may according to the invention be formed in any suitable way, e.g. the connectors may be have different forms.

Fig. 8 shows the assembly joint 92 in cross section. The non-return valve 112 is placed in the inlet section, closing the short inlet connector 105. The short outlet connector 107 is showed continuing through the assembly joint 92.

According to the invention suitable materials for forming the device are preferably different polymers but other materials may also be applied. Preferably the material is polyethylene (PE), polypropylene (PP), ethylvinylacetate (EVA) or polyvinylchloride (PVC).

The first part of the assembly joint (92) may be made from a mouldable material, and most preferable from a polyolefin such as polyethylene (PE), polypropylene (PP), modified polyethylene, polyvinylchloride (PVC) or polyurethane (PUR).

The second part (112) of the assembly joint may be made from a polyolefin, polyvinylchloride (PVC), polyurethane (PUR), silicone or modified polyethylene. In a second aspect, the invention relates to a method for producing a urine collection bag comprising the steps of mounting a short tube or tube section which is secured onto an assembly joint with three connections, whereafter the assembly joint is placed between two walls so that two of the connections are outside the edge of the walls and the connection with the short tube section turning inwards between the walls, said walls and assembly joint are secured to each other, the walls are secured together along the contour in order to form a

bag so that the end of the short tube section is in the bottom part of the bag and an optionally soft backing is secured onto one of the walls, a short flexible inlet tube is secured on one of the free connections on the assembly joint and a non-return valve is secured onto the inlet tube, whereafter a connector is optionally secured onto the inlet tube, a flexible outlet tube is secured onto the last connection of the assembly joint and an outlet valve is finally secured onto the outlet tube.

In a third aspect the invention relates to an assembly joint comprising a first part forming an inlet-section and an outlet section for use in a collection bag, which collection bag is made of at least two sheets joined at the periphery of the collection bag and the assembly joint is placed at the periphery of the collection bag and fastened between the sheets at the periphery which assembly joint comprises two parts, a first part made of a dimensionally stable material through which fluid can pass, and a second part made of a resilient material which part in a closed position completely covers the passage through which the fluid can pass through the first part and where the second part has a plate like form and is fastened to a surface of the first part which surface faces the inside of the collection bag and surrounds the fluid inlet section where from fluid enters the collection bag.

In a fourth aspect the invention relates to the method for producing an assembly joint for use in a urine collection bag, said assembly joint comprising a first part forming the inlet section and the outlet section of the bag, and a second part where the first part is made by moulding and the second part is made in an appropriate size and material whereafter the second part is fastened to a surface of the inlet section of the first part, which surface faces the inside of the collection bag and is penetrated by a fluid opening, through which fluids enter the collection bag, and the second part is fastened in such a way that it covers the fluid opening of the inlet section completely and thus forming a non-return valve.

Further the urine collection bag may be packed.

EXPERIMENTAL PART

Example

Manufacturing of a urine collection bag of the invention.

A collection bag according to Fig. 1 and 2 was manufactured. A 130 mm long Ø8
5 flexible tube 17 is pressed onto one leg on a pipe-shaped Y-piece 13, then a 900
mm long Ø8 mm flexible outlet tube 14 is pressed onto the other leg of the
Y-piece 13. This is the leg which forms an extension of the leg upon which the
130 mm long tube section 17 is mounted. A 50 mm long flexible inlet tube 10, in
which a non-return valve 12 is mounted and which is formed as a flap valve, is
10 pressed onto the last leg of the Y-piece 13 and then a connector 11 is pressed
onto the free end of the inlet tube 10. The Y-piece 13 is now placed between two
150 my walls so that the 130 mm long tube section 17 is placed between the two
walls and the inlet tube 10 and the outlet tube 14 are placed outside the edge 9
of the walls. The Y-piece 13 is welded onto the walls by means of ultrasound and
15 then the walls are welded together along the contour with a pulsation welder so
that the walls form a bag 8 where the internal 130 mm long tube 17 ends in the
lowest point 18 of the bag 8. This bag 8 has a capacity of 900 ml. Finally a
sliding valve 15 is pressed on the free end of the 500 mm long outlet tube 14.

Use of the urine collection bag prepared according to the Example

20 The urine collection bag 1 from example 1 was provided with straps. The bag
was then placed on a users leg 3a by fastening the straps around his leg, then a
urisheath 6 was applicated on the penis of the user and the inlet 5 was
connected to the urisheath 6. The user 2 was dressed and the outlet tube 7 was
placed inside the waist of the trousers. Before placing the outlet tube it was
25 checked that the valve 15 of the outlet 7 was in the closed position. Then the
person 2 was lifted into his wheelchair 4. After a couple of hours the bag 8 was
almost full, and the user 2 emptied the bag in the toilet bowl, by gripping the
outlet with one hand, placing the one end of the outlet with the valve in a open

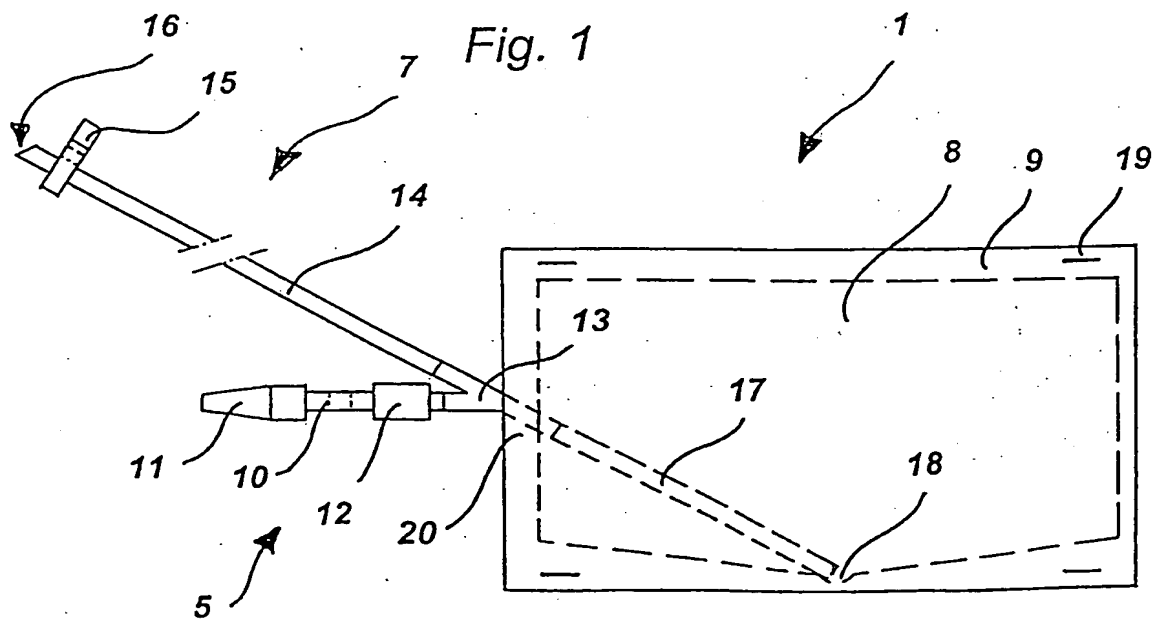
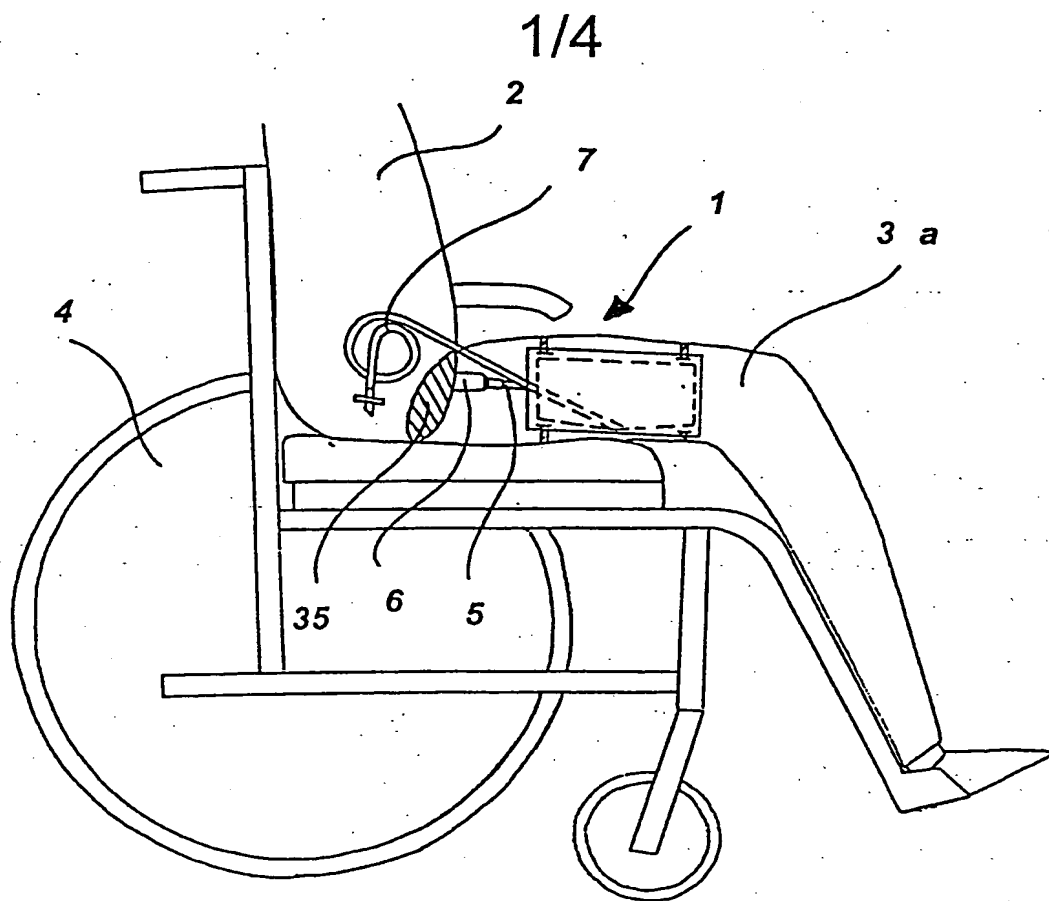
position in the toilet in a horizontally lower position than the urine collection bag. Then the user squeezed the bag for about 2 seconds with the other hand and the urine started to flow and emptied the bag. After emptying the urine collection bag the user wiped the mouth of the outlet with a piece of paper, closed the valve and
5 placed the outlet under the waist of his trousers.

The invention has been described with reference to examples of specific embodiments thereof. Many modifications can be carried out without thereby deviating from the scope of the invention being defined by the scope of the appended claims.

CLAIMS

1. A urine collection bag (1, 21, 41, 61, 81) comprising front and rear walls formed of polymer material, said walls having edges sealed together, an inlet (5, 25, 45, 65, 85) for transporting urine into the urine collection bag, an outlet (7, 27, 47, 67, 87) for emptying urine from the collection bag, said outlet comprising a siphon (17, 57, 97) and is provided with an outlet valve (15, 55, 75, 95), wherein the inlet (5, 25, 45, 65) and outlet (7, 27, 47, 67) have a common lead-in in the bag.
2. A urine collection bag as claimed in claim 1, wherein the inlet (5, 25, 45, 65) and the outlet (7, 27, 47, 67) form a common tube member communicating between the substantially lowest point (18, 58, 78) of the urine collection bag and the point where the inlet is connected to the outlet device.
3. A urine collection bag according to claim 2, wherein the inlet, the outlet and the common tube member are connected by a Y- or T-shaped connector (13).
4. A urine collection bag as claimed in any of the preceding claims, wherein the inlet (5, 25, 45, 65, 85) is provided with a non-return valve (12, 52, 72, 112).
5. A urine collection bag according claim 1, characterised in that the inlet (5) and the outlet (7) are connected to each other by an assembly joint.
6. A urine collection bag as claimed in claim 5, wherein the assembly joint (92) is arranged between the two walls of the bag (88) at the periphery of same, and wherein the assembly joint comprises a non-return valve (112).
7. An assembly joint for a urine collection bag comprising an inlet and an outlet, wherein the assembly joint (92) comprises two parts, a first part made of a dimensionally stable material and comprising an inlet section and an outlet section through which fluid can pass, and a second part (112) made of a resilient material which part in a closed position completely covers the inlet section through which the fluid enters the collection bag through the first part, and

wherein the second part has a plate like form and is secured to a surface of the first part which surface faces the inside of the collection bag and surrounds the inlet section through which fluid enters the collection bag.



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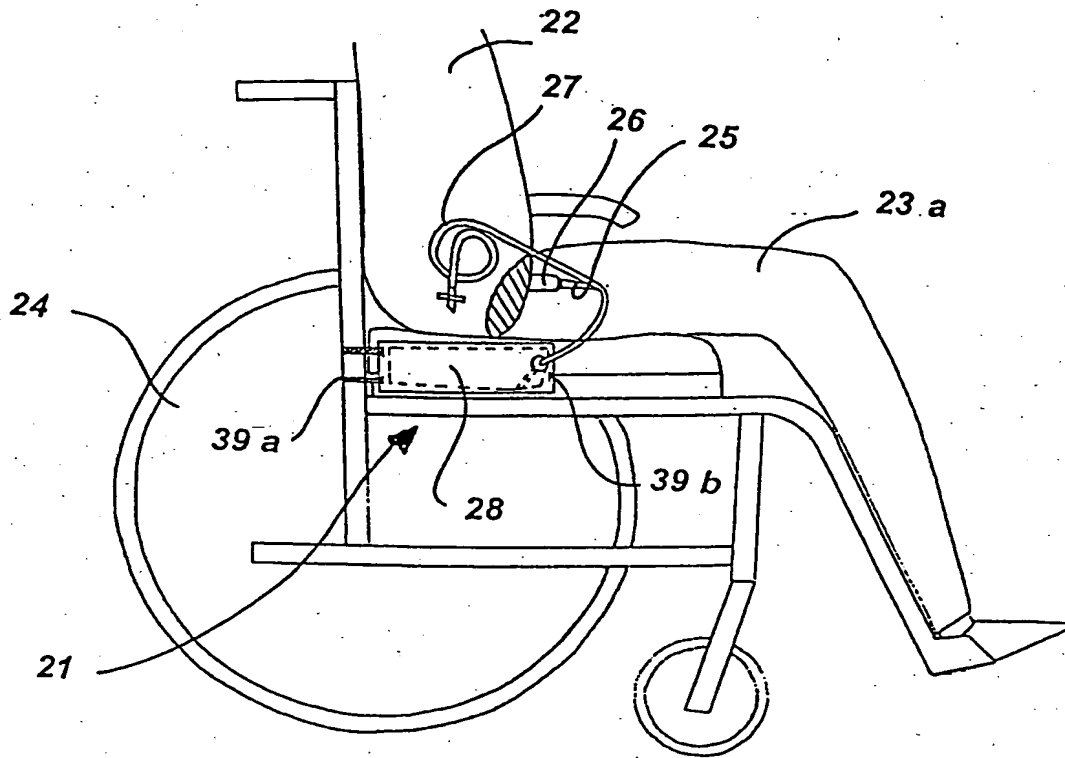


Fig. 3

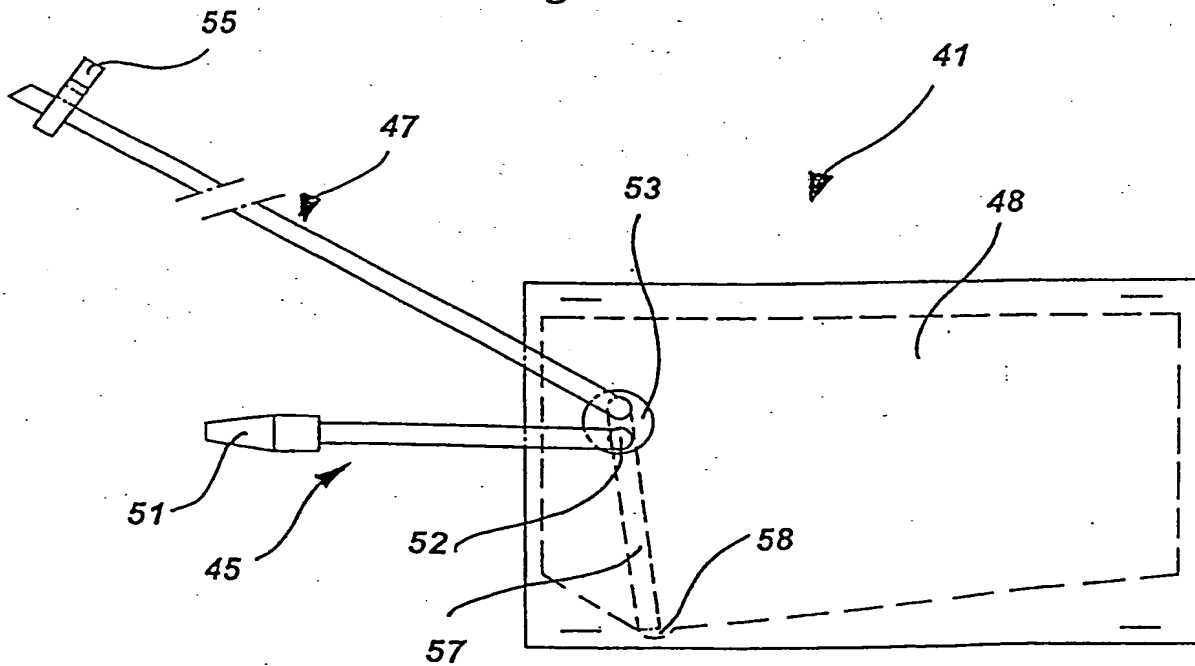


Fig. 4

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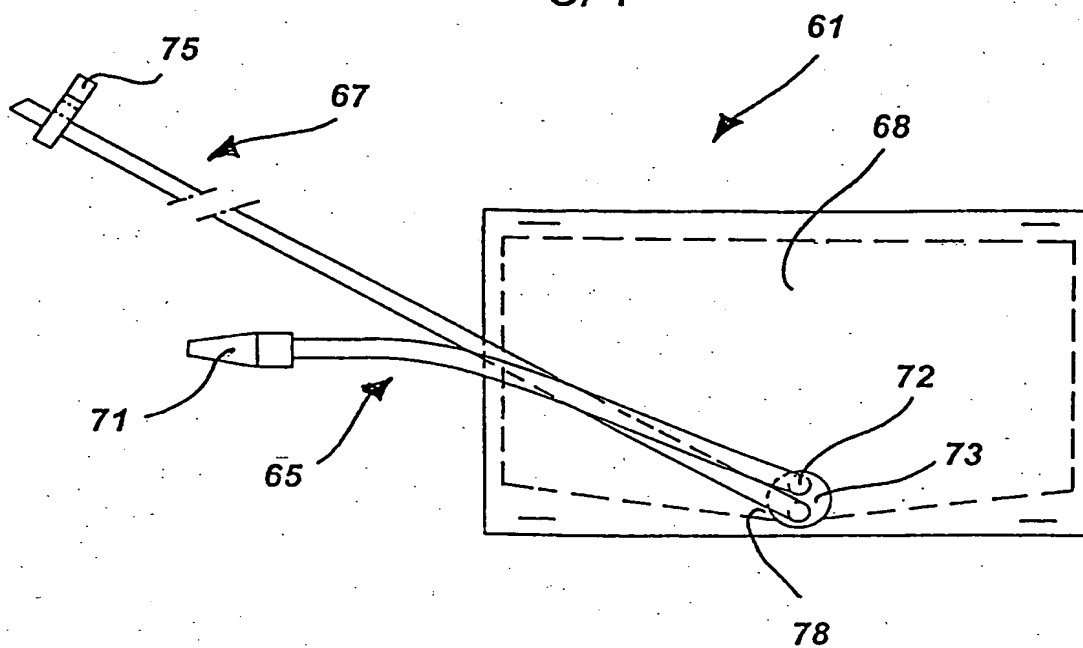


Fig. 5

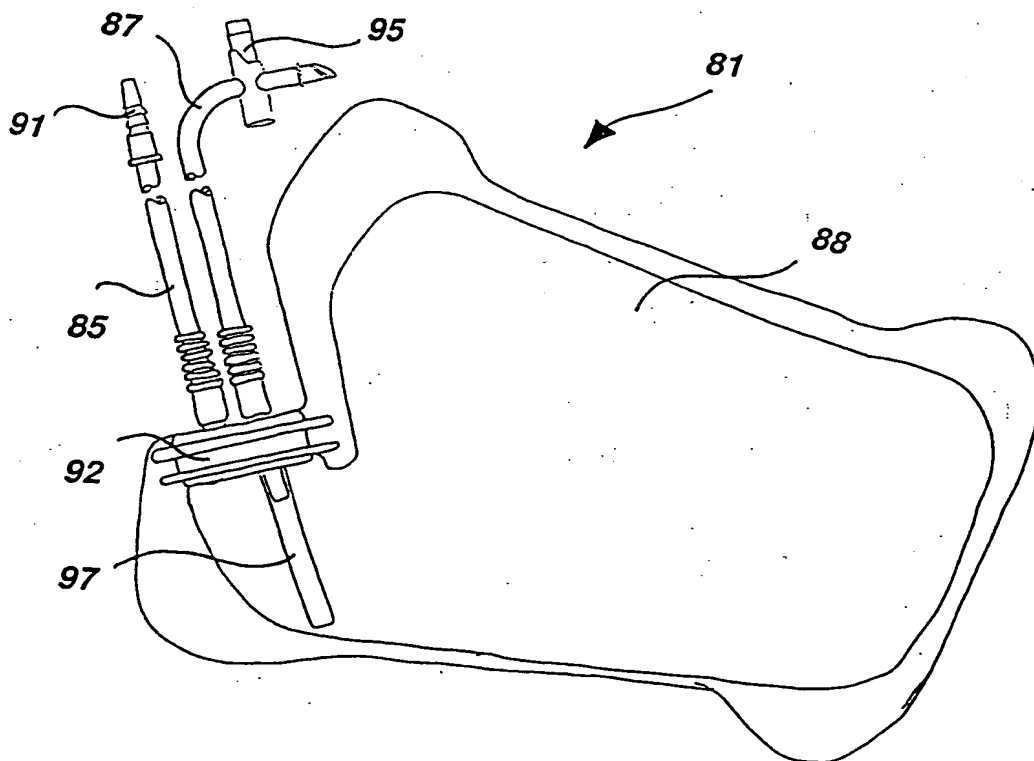


Fig. 6

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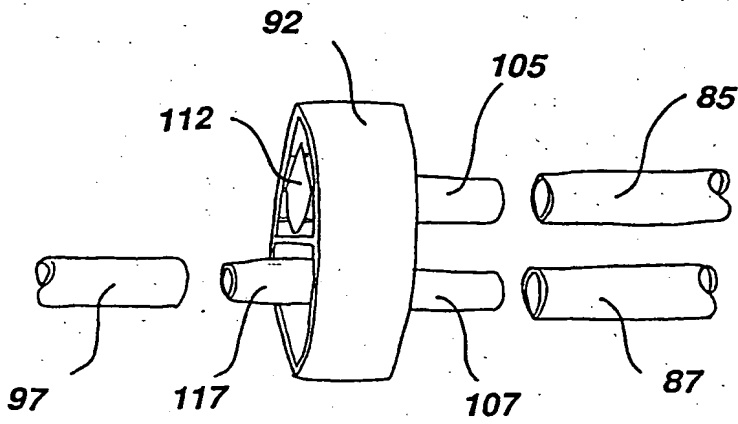


Fig. 7

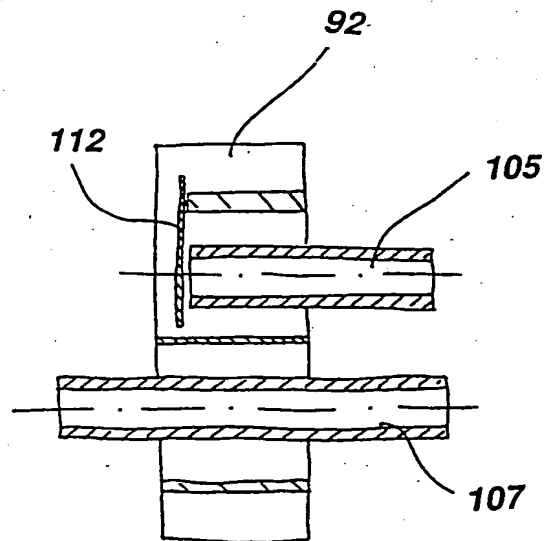


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 98/00479

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61F 5/451 // A61F 5/44 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPODOC, WPI		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 32498 A (H.PFAU. IN FIRMA HEINRICH REIM), 12 March 1885 (12.03.85), page 2, line 4 - line 13, figure 1 --	1-7
A	EP 0136019 A (CRAIG MEDICAL PRODUCTS LIMITED), 3 April 1985 (03.04.85), figure 1 --	1
A	US 4084593 A (JARUND), 18 April 1978 (18.04.78), column 2, line 54 - line 67, figure 1 -- -----	1
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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International application No.

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